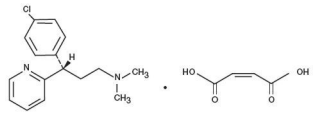
DEXCHLORPHENIRAMINE MALEATE - dexchlorpheniramine maleate solution
Morton Grove Pharmaceuticals, Inc.

Rx only

DESCRIPTION

Each 5 mL (teaspoonful) contains:
Dexchlorpheniramine Maleate, USP. . . . . 2 mg
Alcohol . . . . . not more than 7.0%
Dexchlorpheniramine Maleate, USP, an antihistamine agent, is a white, odorless crystalline powder that is freely soluble in water. The molecular formula is $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$, designated chemically as (+)-2-[*p*-Chloro-α-[2-(dimethylamino)ethyl]benzyl]pyridine maleate (1:1).



M.W. 390.86

Inactive Ingredients: Citric Acid; Dehydrated Alcohol; FD&C Red No. 40; Glycerin; Liquid Sugar; Menthol; Methylparaben; Natural and Artificial Orange Juice Flavor; Propylene Glycol; Propylparaben and Purified Water. **May also** contain Sodium Citrate for pH adjustment. The pH range is between 5.0 and 6.5.

CLINICAL PHARMACOLOGY

Dexchlorpheniramine maleate is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

INDICATIONS AND USAGE

Perennial and seasonal allergic rhinitis
Vasomotor rhinitis
Allergic conjunctivitis due to inhalant allergens and foods
Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
Amelioration of allergic reactions to blood or plasma
Dermographism
As therapy for anaphylactic reactions **adjunctive** to epinephrine and other standard measures after the acute manifestations have been controlled.

CONTRAINDICATIONS

Use in Newborn or Premature Infants

This drug should not be used in newborn or premature infants.

Use in Nursing Mothers

Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease

Antihistamines **should NOT** be used to treat lower respiratory tract symptoms including asthma.
Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to dexchlorpheniramine maleate or other antihistamines of similar chemical structure

Monoamine oxidase inhibitor therapy (See **Drug Interaction** section)

WARNINGS

Antihistamines should be used with considerable caution in patients with:

Narrow angle glaucoma

Stenosing peptic ulcer

Pyloroduodenal obstruction

Symptomatic prostatic hypertrophy

Bladder neck obstruction

Use in Children
In infants and children, especially, antihistamines in **overdosage** may cause hallucinations, convulsions, or death.
As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

Use in Pregnancy
Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants
Dexchlorpheniramine Maleate, USP has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

Use in Activities Requiring Mental Alertness
Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Use in the Elderly (approximately 60 years or older)
Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

PRECAUTIONS
Dexchlorpheniramine Maleate, USP has an atropine-like action and, therefore, should be used with caution in patients with:
History of bronchial asthma

Increased intraocular pressure

Hyperthyroidism

Cardiovascular disease

Hypertension

Drug Interaction
MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

ADVERSE REACTIONS
1. **General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and the throat.

2. **Cardiovascular System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.

3. **Hematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.

4. **Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.

5. **G.I. System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.

6. **G.U. System:** Urinary frequency, difficult urination, urinary retention, early menses.

7. **Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

OVERDOSAGE
Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms—dry mouth, fixed, dilated pupils, flushing, and gastrointestinal symptoms may also occur.
If vomiting has not occurred spontaneously the patient should be induced to vomit. This is best done by having the patient drink a glass of water or milk after which the patient should be made to gag. Precautions against aspiration must be taken, especially in infants and children.
Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis and therefore, are valuable for their action in rapid dilution of bowel content.

Stimulants should **not** be used.
Vasopressors may be used to treat hypotension.

DOSAGE AND ADMINISTRATION
DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

Recommended Dosage
Adults and Children 12 years of age and older: 2 mg (1 teaspoonful)
Children 6 to 11 years: 1 mg (1/2 teaspoonful)
Children 2 to 5 years: 0.5 mg (1/4 teaspoonful)
Doses are generally given every 4 to 6 hours.

HOW SUPPLIED
Dexchlorpheniramine Maleate Oral Solution, USP 2 mg/5 mL is supplied as a red-orange colored, orange flavored liquid in the following sizes:
4 fl oz (118 mL)
16 fl oz (473 mL)
128 fl oz (3785 mL)

RECOMMENDED STORAGE
Store at 20 °–25 °C (68 °–77 °F) [See USP Controlled Room Temperature].
Dispense in a tight, light-resistant container as defined in the USP, with child-resistant closure.

Rx Only
Product No.: 8539
Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053
A50-8539-16
REV. 07-05